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10/551,282	08/21/2006	Danuta Ciok	2003004-US	1573
69289	7590	08/11/2011		
COLOPLAST A/S			EXAMINER	
Attention: Corporate Patents			KIDWELL, MICHELE M	
Holtedam 1				
DK-3050 Humleback,			ART UNIT	
DENMARK			PAPER NUMBER	
			3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@coloplast.com

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Office Action Summary

Application No.

10/551,282

Applicant(s)

CIOK ET AL.

Examiner

Michele M. Kidwell

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 9, 10, 13, 14, 16 and 21-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 4, 5, 9, 10, 13, 14, 16 and 21-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed June 1, 2011 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the applicant has added claim 23 which recites portions that are each located at an equal radial distance from the hole .

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites portions that are each located at an equal radial distance from the hole. This limitation is not supported by the originally filed specification. The

examiner notes applicant's remarks regarding the support for this limitation. While, applicant relies on figures 1 - 4 to support the limitation, the applicant is reminded that proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale. See MPEP 2125.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 181 910 A1.

With reference to claims 1 and 21, EP 1 181 910 A1 (hereinafter '910) discloses a one-piece ostomy appliance comprising a bag having a front wall and a rear wall (figure 1) and an opening disposed in the rear wall of the bag that is configured to receive a stoma [0014]. The appliance also includes an adhesive wafer with an alignable opening having a skin securing adhesive layer one side and a second side positioned to abut the rear wall of the bag as set forth throughout the disclosure. A release liner is taught in [0016]. The second side includes a first permanently secured portion and a second unsecured portion that includes an adhesive layer for selective securement as set forth throughout the disclosure, see especially [0010-0011].

Claims 13 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Whiteside (US 2001/0020156).

With reference to claims 13 - 14, Whiteside discloses an ostomy appliance having a bag (11) as claimed including an adhesive wafer (21,22) that is configured to be secured as claimed [0022] and including a permanently attached first part and a second attachable part as well as a removable barrier positioned as claimed as set forth throughout the disclosure, see especially [0020-0024]. The edge parts are configured for permanent sealing as set forth in [0020-0021] and [0024].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 – 5 and 9 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 181 910 A1 in view of Thomas (4,865,594)

The difference between '910 and claim 4 is the provision that the ostomy appliance comprises a stiffening element.

Thomas provides the ostomy appliance with a stiffening element to which first and second parts of the bag are secured as set forth in col. 3, lines 23 – 41.

It would have been obvious to one of ordinary skill in the art to provide the ostomy appliance of '910 with a stiffening element as taught by Thomas because the use of such facilitates adhesion and/or reduces skin irritation as taught by Thomas in col. 3, lines 16 – 41.

With reference to claims 5 and 9 – 10, see col. 3, lines 16 – 41 and figure 3 of Thomas.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whiteside (US 2001/0020156) A1 in view of Thomas (4,865,594)

The difference between Whiteside and claim 16 is the provision that the ostomy appliance comprises a stiffening element.

Thomas provides the ostomy appliance with a stiffening element to which first and second parts of the bag are secured as set forth in col. 3, lines 23 – 41.

It would have been obvious to one of ordinary skill in the art to provide the ostomy appliance of Whiteside with a stiffening element as taught by Thomas because the use of such facilitates adhesion and/or reduces skin irritation as taught by Thomas in col. 3, lines 16 – 41.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 181 910 A1 in view of Whiteside (US 2001/0020156).

With reference to claim 22, '910 teaches the invention substantially as claimed.

The difference between '910 and claim 22 is the provision that the adhesive layer allows the second portion of the second side of the adhesive wafer to be removed from the rear wall of the bag and allows the second portion of the second side of the adhesive wafer to be resealed to the rear wall of the bag.

Whiteside teaches an adhesive layer that allows the second portion to function as claimed as set forth in [0020-0024].

It would have been obvious to one of ordinary skill in the art to provide '910 with a second portion as taught by Whiteside because such both prior art references are utilizing a temporary seal to facilitate separation of the applicant as desired.

Response to Arguments

Applicant's arguments with respect to claims 13 – 14, 16 and 22 – 23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed June 1, 2010 have been fully considered but they are not persuasive.

With respect to claim 1, the examiner contends that the applicant's arguments are more specific than the claim language. The applicant argues that the adhesive layer of '910 has a backing sheet attached to it. This does not preclude the fact that the adhesive layer is present and positioned as claimed. There is no positive recitation of the adhesive actually being secured in claim 1. The layer only needs to be positioned to perform the function and the adhesive of '910 is positioned as such as set forth in the figures. The examiner also notes that '910 does not anticipate an entire surface being

covered with the backing layer because bonds 25 connect the outer ring (21) to the rear wall (11) as set forth in col. 3, lines 16 – 19 thereby providing a direct attachment between the ring and the wall without the use of the backing layer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele M. Kidwell whose telephone number is (571)272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele Kidwell/
Primary Examiner, Art Unit 3761